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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,840	03/06/2001	Thomas Specht	SCH 1781	5598

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EXAMINER

ZITOMER, STEPHANIE W

ART UNIT PAPER NUMBER

1634

DATE MAILED: 08/15/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/673,840

Applicant(s)

SPECHT ET AL.

Examiner

Stephanie Zitomer

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 1-23,25,27-31 and 33-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23,24,26 and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) Z 6) ☐ Other:

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DETAILED ACTION

Response to election with traverse

1. Applicant's election with traverse of Group IV, claims 23, 24, 26 and 32 in Paper No. 9, filed June 13, 2002, is acknowledged. The traversal is on the ground(s) that the examiner "has not established an undue search burden". This is not found persuasive because Lack of Unity in a 371 application is based on PCT Rules 13.1 and 13.2. The requirement for election of one invention constituting a single nucleotide sequence was made under 35 U.S.C. 121 for convenience. However, each different nucleotide sequence constitutes a different invention under PCT Rules 13.1 and 13.2 as well. Thus, "search burden" is not a basis for lack of unity in a 371 application.

The requirement is still deemed proper and is therefore made FINAL. Claims 1-23, 25, 27-31 and 33-38 are withdrawn from prosecution as being drawn to nonelected inventions.

Abstract

2. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Priority information

3. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

Other informalities

4. The disclosure is objected to because of the following informalities:

(a) All parts of the application must be in English. There are tables in German which appear to be duplicates of tables in English. The non-English tables should be deleted or rendered in English.

(b) The correct sequence identifier is **SEQ ID NO:** or the plural **SEQ ID NOS:**. Appropriate correction is required.

Rejection under 35 U.S.C. 101: Lack of utility

35 U.S.C. 101 reads as follows:

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Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 23, 24, 26 and 32 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. The claimed polypeptide partial sequences are not supported by a specific asserted utility because the disclosed use as "tools for finding active ingredients against the bladder tumor" (specification, page 7) is a general use in that other polypeptides and proteins as well as nucleic acids can be used in screening assays for bladder cancer drugs. In other words, the asserted utility is not specific to the claimed polypeptides. It would have been known to one of skill in the art to use the polypeptides to make antibodies and to use the antibodies to search for the full length proteins. However, this, too, is a generic utility which does not specifically apply to the claimed polypeptides in that it may be performed with any polypeptide. There can be no well-established utility for the polypeptides as the claimed sequences were not found in the prior art. Notably, the specification is directed to obtaining nucleotide sequences by computer alignment and manipulation of database sequences and the polypeptide sequences have been obtained by "assignment" (specification, page 132). Furthermore, the claimed "pharmaceutical agent" of claim 32 lacks specific and substantial utility because the polypeptide sequences contained therein have not been shown to be associated with any particular disease or condition. Thus, the claimed subject matter has no substantial, i.e., no practical or "real world", utility.

6. Claims 23, 24, 26 and 32 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Rejection under 35 U.S.C. 112, first paragraph: Lack of written description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly

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connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 23, 24, 26 and 32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In view of the confusing claim language (see below at paragraph 8.) the claims appear to be drawn to polypeptide sequences that extend beyond the sequences disclosed in the specification. However, no information as to the full length of these sequences is provided. The specification only describes how the sequences may be "automatically lengthened" via computer program manipulations of database sequences (pages 131-132, Example 3). Regarding the claimed 80% and 90% homologous sequences of claims 24 and 26, the specification provides no information whatsoever as to which amino acids of the SEQ ID NO: sequences may be deleted or substituted nor even whether such homologous sequences would be required to have the same activity, if an activity were to be determined, as the claimed amino acid sequence. The specification further fails to describe how to use the "pharmaceutical agent" of claim 32 and for what specific purpose in that "gene therapy for treatment of bladder tumors" and "for production of a pharmaceutical agent for treatment of bladder tumors" (page 7) are general applications not specific to the claimed polynucleotides or to any particular type of bladder tumor. In addition to enablement the first paragraph of 112 requires a "written description". As set forth by the Court in *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, the written description must convey to one of skill in the art "with reasonable clarity" that as of the filing date applicant was in possession of the claimed invention. For all of the foregoing reasons, it is clear that applicant was not in possession of the claimed polypeptides and pharmaceutical agent at the time the application was filed.

Rejections under 35 U.S.C. 112, second paragraph: Indefiniteness

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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8. Claims 23, 24, 26 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) The claims are confusing in the recitation "partial sequences" because it is unclear whether the claim is drawn to sequences that are parts of the recited SEQ ID NO: sequences or whether the SEQ ID NO: sequences are themselves partial sequences of larger sequences. Note that "according to" is interpreted as open transitional language.

(b) In claims 24 and 26, the antecedent subject of "these sequences" is unclear in view of the confusion noted above at (a).

Prior art of interest

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The PCT publication, WO 96/35808, discloses polypeptides and methods for obtaining polypeptides useful for diagnosis and treatment of squamous cell and bladder carcinomas.

Conclusion

10. **No claim is allowed.** The claims are free of the prior art.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephanie Zitomer whose telephone number is (703) 308-3985. The examiner can normally be reached on Monday through Friday from 9:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152. The official fax phone number for this Group is (703) 308-4242. The unofficial fax number is (703) 308-8724. The examiner's Rightfax number is 703-746-3148.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196. For questions and requests relating to formal matters contact Patent Analyst Tiffany Tabb at 703-605-1238.



Stephanie Zitomer, Ph.D.
August 12, 2002

**STEPHANIE W. ZITOMER
PRIMARY EXAMINER**